



**Drug Utilization Review Board Meeting
Meeting Agenda, Open Session
April 11, 2012 10:00 a.m.**

HP Enterprise Services ~ Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, Kansas 66619

Board Members

Dennis Grauer, PhD	Tim Heston, DO
John Kollhoff, PharmD	Judy McDaniel Dowd, PA-C
Daniel Sutherland, RPh	Kevin Waite, PharmD
Roger Unruh, DO	

KDHE-DHCF Staff

Shelly Liby	Kelley Melton, PharmD
Shea Robinson	

HP Enterprise Services / HID Staff

Karen Kluczykowski, RPh	Pam Girard, RN
Debra Quintanilla, RN	Lisa Todd, RPh
Nicole Churchwell, PharmD	

ACS Staff

Larry Dent, PharmD, BCPS	Bethany Noble, CPhT
--------------------------	---------------------

- I. Call to Order
- II. Announcements
- III. Old Business

A. Review and Approval of October 12, 2011 Meeting Minutes

- IV. New Business

A. Xarelto® (rivaroxaban)

In October 2011, the DUR Board voted to place a day supply limit of 35 days on rivaroxaban based upon the package insert and indications available at that time. In November 2011, rivaroxaban received approval for a new indication for use in atrial fibrillation. The new indication extends the amount of time a patient would use rivaroxaban; therefore, DHCF has decided not to move forward with restrictions on rivaroxaban.

- i. Update for DUR Board
- ii. Board Discussion

B. Pradaxa® (dabigatran)

In June 2011, the DUR Board voted to place quantity and day supply limits on dabigatran based upon the storage and handling information in the package insert available at that time. In October 2011, new information became available that extended the expiration of the medication from 30 days to 4 months after opening the bottle, if the drug is stored in the original container. Based upon the new information available, DHCF has decided not to move forward with restrictions on dabigatran.

- i. Update for DUR Board
- ii. Board Discussion

C. Bile Acid Sequestrants

Bile Acid Sequestrants include cholestyramine (Questran®, Questran Light®, and Prevalite®), colestipol (Colestid®), and colesevelam (Welchol®). These agents are used to treat hypercholesterolemia by binding intestinal bile acids. Bile Acid Sequestrants are a new PDL class approved by the PDL committee on March 14, 2012. It is recommended that PDL non-preferred criteria be approved for the bile acid sequestrants.

- i. PDL Non-Preferred Agent Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

D. Incretin Mimetics

Incretin mimetics include Byetta® (exenatide), Victoza® (liraglutide), and Bydureon® (exenatide extended-release). These agents are glucagon-like peptide-1 (GLP-1) receptor agonist that are indicated as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Incretin Mimetics are a new PDL class. Byetta and Bydureon were approved for inclusion by the PDL committee on March 14, 2012. Victoza was not approved until further studies could be evaluated. It is recommended that PDL non-preferred criteria be approved for the Incretin Mimetics. Your packets include the package inserts and proposed prior authorization criteria.

- i. PDL Non-Preferred Agent Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

E. Bydureon® (exenatide extended-release)

Bydureon is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Bydureon is not recommended as first-line therapy. Other GLP-1 receptor agonists include Byetta (exenatide) and Victoza (liraglutide), which has approved prior authorization criteria requiring a look back for maximum tolerated doses of a sulfonylurea or metformin. It is recommended that Bydureon be added to the current criteria. Your packets include the package insert and proposed prior authorization criteria.

- i. New Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

F. Onfi® (clobazam)

Onfi is a new benzodiazepine indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. Due to the potential for off-label use and abuse of this drug, the DUR Board is asked to approve diagnosis restrictions for use in patients with epilepsy.

- i. Diagnosis Restrictions
- ii. *Public Comment
- iii. Board Discussion/Action

G. Long-Acting Opioids Dose Optimization (Nucynta ER® (tapentadol))

Nucynta ER is an opioid analgesic indicated for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. All long-acting opioids require prior authorization above the DUR approved units/day. It is recommended that Nucynta ER be added to other long-acting opioids limitation criteria.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

*Public Comment is limited to five minutes per product; additional time will be allowed at the Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

**** This agenda is subject to change.**

H. Botox® (onabotulinumtoxinA)

The botulinum toxin criteria were last approved in January 2011 by the DUR board. In September 2011, the FDA approved urinary incontinence as a new indication for Botox. It is recommended that current criteria be revised to include use of Botox for urinary incontinence.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

I. Prolia® (denosumab)

In October 2010, the DUR Board approved clinical prior authorization criteria for Prolia. At that time, the only FDA approved indication was for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture or multiple risk factors for fracture; or patients who have failed or are intolerant to other osteoporosis therapy. In September 2011, two new indications were approved; these include treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer and treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. The DUR Board is asked to approve revised clinical prior authorization criteria that include the two new indications.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

J. Mozobil® (plerixafor)

Mozobil was last approved by the DUR Board in March 2009. It is indicated to be used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's Lymphoma (NHL) and multiple myeloma (MM). The prior authorization criteria are being updated to reflect the most recent package insert.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

K. Remicade® (infliximab)

The Remicade prior authorization criteria were last revised in June 2011. In September 2011, the indication for ulcerative colitis was expanded from patients 18 years of age and older to include patients 6 years of age and older. The prior authorization criteria are being revised to reflect this change.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

L. Orencia® (abatacept)

Orencia is indicated for rheumatoid arthritis and juvenile idiopathic arthritis. Orencia prior authorization criteria were last approved by the DUR board in November of 2008. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

*Public Comment is limited to five minutes per product; additional time will be allowed at the Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

**** This agenda is subject to change.**

M. Kineret® (anakinra)

Kineret is indicated for rheumatoid arthritis. Kineret prior authorization criteria were last approved in April 2004 by the DUR board. The manufacturer recommends that neutrophil counts be assessed prior to initiating Kineret, and while receiving Kineret, monthly for 3 months, and thereafter quarterly for a period up to 1 year. It is recommended that current criteria be revised to include laboratory monitoring criteria, TB skin test, and criteria to look for a history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

N. Actemra® (tocilizumab)

Actemra was last reviewed by the DUR Board in April 2010; since that time an indication for juvenile idiopathic arthritis was approved by the FDA. The prior authorization criteria are being revised to reflect the new indication, update the appropriate lab monitoring for renewals, and add criteria that look for the history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

O. Simponi® (golimumab)

Simponi is indicated for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Simponi was last approved by the DUR board in January 2011. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

P. Stelara® (ustekinumab)

Stelara is indicated for plaque psoriasis. Stelara was last approved by the DUR board in January 2011. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

Q. Rituxan® (rituximab)

Rituxan was last approved by the DUR Board in June 2011; it is being revised to include a criteria check for the history of another biologic agent as well as renewal criteria for appropriate lab monitoring.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

R. Cimzia® (certolizumab)

Cimzia is indicated for rheumatoid arthritis and Crohn's disease. Cimzia was last approved by the DUR board in January of 2010. It is recommended that current criteria be revised to include criteria to look for a history of another biologic agent.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

*Public Comment is limited to five minutes per product; additional time will be allowed at the Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

**** This agenda is subject to change.**

S. Tysabri® (natalizumab)

Tysabri is indicated for the treatment of multiple sclerosis and Crohn's disease; it was last reviewed by the DUR Board in January 2010. The prior authorization criteria are being revised to include a criteria check for a history of another biologic agent and evaluation for latent tuberculosis with a TB skin test.

- i. Revised Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

T. Kalydeco® (ivacaftor)

Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator. It is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene. Kalydeco is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene and has not been studied in other patient populations with CF. Prior authorization criteria is being proposed to include criteria for diagnosis of CF in patients who are 6 years of age or older. Your packets include the package insert and proposed prior authorization criteria.

- i. New Clinical Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion/Action

U. Retro-DUR Intervention Outcomes

Health Information Designs (HID) will present Retro-DUR outcomes for the intervention letters mailed in State Fiscal Year 2011. The five intervention topics that were mailed include: Increased Risk of Serotonin Syndrome, Appropriate ADHD Treatment, Psychotropic Use in Children and Adolescents, History of Drug Abuse, and Appropriate Narcotic Utilization.

- i. Retro-DUR Outcomes Report
- ii. Board Discussion

- V. Medicaid Reform Update
- VI. Selection of New Chairperson
- VII. *Open Public Comment
- VIII. Adjourn

**Lunch will be provided for DUR Board Members
NEXT MEETING: July 11, 2012**

*Public Comment is limited to five minutes per product; additional time will be allowed at the Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

** This agenda is subject to change.